

Patient ID SA00150352	Patient Name TESTINGRNV, H2BR-POSITIVE	Birth Date 1976-02-16	Gender F	Age 45
Order Number SA00150352	Client Order Number SA00150352	Ordering Physician CLIENT,CLIENT	Report Notes	
Account Information C7028846 DLMP Rochester		Collected 24 Jan 2022 14:54		

HER2, Breast Tumor, FISH, Tissue

Result Summary

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Positive with Reflex Testing (See Interpretation)

Interpretation

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This tumor sample is HER2 positive based on the combined review of the dual-probe in situ hybridization (ISH) and reflex HER2 immunohistochemistry (IHC) results.

The initial evaluation demonstrated a HER2/centromere ratio of 1.50 and an average HER2 copy number per cell of 6.3. According to current ASCO/CAP guidelines for HER2 testing in breast cancer, ISH results indicating a HER2/centromere ratio less than 2.0 and an average HER2 copy number of 6.0 or more signals per cell ("Group 3") require additional workup by IHC (1).

IHC was performed on this sample per ASCO/CAP guidelines and was equivocal (results reported separately).

The ISH slide was re-analyzed using areas of IHC-equivocal (2+) staining as a guide. The re-evaluation of the ISH slide demonstrated a HER2/centromere ratio of 1.39 and an average HER2 copy number per cell of 6.3.

This result is interpreted as FISH positive ("Group 3") (1).

References:

1. Wolff, et al., J Clin Oncol, 36(20):2105–2122, 2018

Result

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INITIAL PROBE RESULT:

nuc ish(D17Z1x4–5,HER2x6–7)

HER2/D17Z1 ratio: 1.50

Average HER2 signals per cell: 6.3

Average D17Z1 signals per cell: 4.2

FINAL IHC-GUIDED PROBE RESULT:

nuc ish(D17Z1x4–5,HER2x6–7)

HER2/D17Z1 ratio: 1.39

Average HER2 signals per cell: 6.3

Average D17Z1 signals per cell: 4.5

Reason for Referral

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r/o HER2/neu gene amplification

Specimen

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Tissue, Paraffin, Formalin

Source

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Breast

Tissue ID

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BR-12345

Fixative

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Formalin

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292



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Method

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FISH using probes for HER2 (17q12) and a D17Z1 control probe; reflex testing utilizing IHC-guided focused analysis from the region of 2+ IHC staining. Two technologists score signals in 120 total nuclei (60 nuclei in initial analysis and 60 nuclei by IHC-guided analysis) from invasive or metastatic tumor after confirmation of probe performance by concurrent controls. Scoring method: Manual.

adjunct to existing prognostic clinical and pathologic information for breast cancer patients. This test is not intended to diagnose or screen for breast cancer. Since **only a** portion of the tumor was tested, it is possible that this result may not represent the entire tumor population. Per ASCO/CAP guidelines, HER2 FISH test results are valid for non-decalcified paraffin embedded specimens fixed in 10% neutral buffered formalin between 6 and 72 hours. Results from specimens fixed outside these parameters should be interpreted accordingly.

Disclaimer

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Laboratory Developed Test (LDT). This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It is intended as an

Released By

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Patricia T. Greipp, D.O.

Received: 25 Jan 2022 14:56

Reported: 21 Feb 2022 11:01

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MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292